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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,360	09/25/2003	James C. Powers	820701-1015	7114

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EXAMINER

LEWIS, AMY A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,360	<b>Applicant(s)</b> POWERS ET AL.	
	<b>Examiner</b> Amy A. Lewis	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 9/25/2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 11-14, drawn to a pharmaceutical composition comprising a calpain inhibitor and an anti-hyperproliferative agent, classified in class 530, subclass 345, for example.
- II. Claims 1-4, drawn to a method of treating axonal degeneration of the peripheral nervous system comprising administering a compound of the formula of claim 1, classified in class 530, subclass 345, for example.
- III. Claims 5, 6, and 15-18, drawn to a method of treating neuropathy comprising administering a calpain inhibitor, classified in class 530, subclass 330, for example.
- IV. Claims 7-10, drawn to a method of treating hyperproliferative disorders comprising administering a calpain inhibitor, classified in class 530, subclass 330, for example.
- V. Claims 19-22, drawn to a method of treating calcium-induced cell injury, comprising administering a calpain inhibitor, classified in class 530, subclass 330, for example.

Inventions I and II, I and III, I and IV, and I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:  
(1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case calpain inhibitors can be used in a materially different process of using, such as treating enterovirus and rhinovirus infection (see: Molla A, et al. abstract).

The methods of treating the various disorders of Groups II through V are considered independent and patentably distinct, each from the other, for the following reasons:

Axonal degeneration of the peripheral nervous system (of Group II) is patentably distinct from neuropathy (of Group III), hyperproliferative disorders (of Group IV) such as cancer, and calcium-induced cell injury (of Group V) because they are different disorders with different etiologies and patient populations, and treatment of axonal degeneration of the peripheral nervous system would not be expected to also treat neuropathy (of Group III), hyperproliferative disorders (of Group IV), or calcium-induced cell injury (of Group V).

Neuropathy (of Group III) is patentably distinct from hyperproliferative disorders (of Group IV) such as cancer and calcium-induced cell injury (of Group V) because they are different disorders with different etiologies and patient populations, and treatment of neuropathy (of Group III) would not be expected to also treat hyperproliferative disorders (of Group IV) or calcium-induced cell injury (of Group V).

Hyperproliferative disorders (of Group IV) such as cancer, are patentably distinct from calcium-induced cell injury (of Group V) because they are different disorders with different etiologies and patient populations, and treatment of a hyperproliferative disorder (of Group IV) such as cancer would not be expected to also treat calcium-induced cell injury (of Group V).

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These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and search for one group does not require a search for another group. Therefore, a search and examination of all inventions in one patent application would result in an undue burden.

Restriction for examination purposes as indicated is proper.

### ***Election of Distinct invention***

For the practice of inventions I through V, applicant is also required to elect one specific compound where every variable is identified. Here, each AA<sup>2</sup>-AA<sup>1</sup> is indicated in claim 1 (and used in the practice of the inventions) are D or L amino acids and/or derivatives thereof. Each dipeptide differs from the other, e. g., Ala-Val is not the same dipeptide as Phe-Phe; the search for one is not a search for the other; and are recognized in the art as having distinct and different core structure.

The election of a distinct compound will be given effect in the event that the Markush-type claims are not found allowable at which time the examination of the claims presented will be limited to the Markush-type claims and claims directed solely to the election made as to the specific distinct compound. The claims directed to nonelected items will be held withdrawn from further consideration. The election is a requirement for restriction under 35 USC 121 to patentably distinct and/or independent inventions. *In re Herrick*, 1858 CD 1, and *In re Joyce*, 19558 CD 2.

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Applicant's response must include a provisional election of one of Groups I through V and one specific compound. The election must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Contact Information:


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis  
Patent Examiner  
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